U.S. Department of Justice

Michael J. Sullivan
United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

John Joseph Moakley United States Courthouse
Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210

October 18, 2007

Mr. T. Mark Flanagan, Esq.
McKenna Long & Aldridge
1900 K Street, NW
Washington, DC 20006

Re: United States v. Bryan Corporation

Dear Mr. Flanagan:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts, the Office of Consumer Litigation, United States Department of Justice (collectively, "the Government"), and your client, Bryan Corporation ("Defendant"), in the above-captioned case. The Agreement is as follows:

1. Plea to Information

At the earliest practicable date, Defendant agrees to waive indictment and plead guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C), 11(c)(1)(A), to a three-count Information attached hereto as Exhibit A. Count One charges the Defendant with -- between in or about March 1997, and on or about September 5, 2000 -- introducing for delivery into interstate commerce various quantities of a misbranded drug (sterile "bulk talc" powder, Product #1690), in violation of 21 U.S.C. §§ 331(a), 333(a)(1). Count Two charges the Defendant with -- between in or about December 1997, and in or about November 2000 -- introducing for delivery into interstate commerce various quantities of an adulterated device (barium sulfate), in violation of 21 U.S.C. § 331(a), 333(a)(1). Count Three of the Information charges Defendant with -- between on or about March 1, 2000, and March 9, 2000 -- corruptly endeavoring to influence, obstruct, and impede an agency proceeding in violation of 18 U.S.C. § 1505. Defendant expressly and unequivocally admits that it committed these offenses and that, with respect to Count Three, it acted knowingly and corruptly. Defendant expressly and unequivocally further admits that it is in fact guilty of these offenses. Defendant agrees to waive venue, to waive any applicable statutes of limitations, and to waive any legal or procedural defects in the Information.

2. Penalties

Defendant faces the following maximum penalties with respect to the counts of conviction:

a. Count One (21 U.S.C. §§ 331(a), 333(a)(1)):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571 (c)(5), (d). Given Defendant's sales of bulk talc totaled $3,767,585, the maximum possible fine in connection with this Count is $7,535,170.

ii. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2).

iii. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556, 3663.

iv. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

b. Count Two (21 U.S.C. §§ 331(a), 333(a)(1)):

i. A fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571 (c)(5), (d). Given Defendant's sales of barium sulfate totaled $818,772 the maximum possible fine in connection with this Count is $1,637,544.

ii. A term of probation of not more than five (5) years. *See* 18 U.S.C. § 3561(c)(2).

iii. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556, 3663.

iv. A mandatory special assessment of $125. *See* 18 U.S.C. § 3013(a)(1)(B)(iii).

c. Count Three (18 U.S.C. § 1505):

i. A fine of $500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§ 3571 (c)(3), (d).

ii. A term of probation of not less than one (1) year and not more than five (5) years. *See* 18 U.S.C. § 3561(c)(1).

iii. Restitution to any victims of the offense. *See* 18 U.S.C. §§ 3556, 3663.

iv. A mandatory special assessment of $400. *See* 18 U.S.C. § 3013(a)(2)(B).

3. Sentencing Guidelines

The parties agree to jointly take the following positions at sentencing under the United States Sentencing Guidelines ("U.S.S.G."):

a. The parties agree that the Guideline Manual in effect as of November 1, 1998, should be used in determining Defendant's sentence. *See* U.S.S.G. § 1B1.11(b)(1) (Nov. 1, 2006).

b. The parties agree that each of Counts One through Three are not covered under U.S.S.G. § 8C2.1 (Nov. 1, 1998), and that pursuant to U.S.S.G. § 8C2.10 (Nov. 1, 1998), the Court should determine an appropriate fine by applying the provisions of 18 U.S.C. §§ 3553 and 3572.

4. Agreed Disposition

The Government and Defendant agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the appropriate disposition of this case is as follows:

a. A criminal fine of $4,514,700 to be imposed as follows:

i. Count One: $3,324,700

ii. Count Two: $ 690,000

iii. Count Three: $ 500,000

Defendant shall pay this fine within five business days of the date of sentencing assuming that the sentencing occurs after January 1, 2008; however, if the sentencing occurs prior to January 1, 2008, then the criminal fine shall be paid by January 15, 2008.

b. Mandatory special assessments totaling $650 pursuant to 18 U.S.C. § 3013, to be imposed as follows:

i. Count One: $125

ii. Count Two: $125

iii. Count Three: $400

c. In light of the Civil Settlement Agreement between Defendant and the United States (which is being signed contemporaneously with this Plea Agreement, and is attached hereto as Exhibit B), which requires payment of $485,300 plus any interest due, the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to the victims in this case given that the hospitals that purchased the products in question either were reimbursed by unknown insurance companies in connection with the procedures in which the products were used or were reimbursed by Defendant during a product recall, and that tracing reimbursements to the various unknown insurance companies and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible. *See* 18 U.S.C. § 3663(a)(1)(B)(ii). Therefore, the United States agrees that it will not seek a separate restitution order as to Defendant as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

d. A term of Probation of between one (1) and five (5) years with conditions to be determined by the Court.

The Government's agreement that the disposition set forth herein is appropriate in this case is based, in part, on Defendant's prompt acceptance of responsibility for the offenses of conviction in this case.

The Government may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement that paragraph 4 constitutes the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, Defendant:

(a) Fails to admit a complete factual basis for the plea;

(b) Fails to truthfully admit its conduct in the offenses of conviction;

(c) Falsely denies, or frivolously contests, relevant conduct for which Defendant is accountable under U.S.S.G. § 1B1.3;

(d) Fails to provide truthful information about its financial status;

(e) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which Defendant is accountable under U.S.S.G. § 1B1.3;

(f) Engages in acts which form a basis for finding that Defendant has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1;

(g) Intentionally fails to appear in Court or violates any condition of release;

(h) Commits a crime; and/or

(i) Attempts to withdraw its plea.

Defendant expressly understands that it may not withdraw its plea of guilty unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

5. No Further Prosecution of Defendant

Other than the charges set forth in the Information (Exhibit A), the Government agrees not to bring any additional federal criminal non-tax charges against Defendant with respect to the conduct covered by the Information or facts currently known to the Government based upon:

a. Defendant's conduct during the FDA regulatory inspection conducted in or about March 2000, to include any subsequent conduct through 2000 relating to this March 2000 inspection;

b. Defendant's conduct in the manufacture, marketing and distribution of sterile talc powder for the treatment of malignant pleural effusion through 2000;

c. Defendant's conduct in the manufacture, marketing and distribution of barium sulfate through 2000; and

d. Defendant's conduct in the manufacture, marketing, and distribution of Sclerosol through 2000, including any failure during this time period to maintain adequate files and/or file appropriate periodic reports to the FDA regarding adverse drug reactions.

This agreement is expressly contingent upon:

a. the guilty pleas of Defendant to the Information attached hereto as Exhibit A being accepted by the Court and not withdrawn or otherwise challenged; and

b. Defendant's performance of all its obligations as set forth in this Agreement and the attached Civil Settlement Agreement.

If Defendant's guilty plea is not accepted by the Court or is withdrawn for any reason, or if Defendant should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void.

The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Bryan Corporation, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the Government.

6. Payment of Mandatory Special Assessment

Defendant shall pay the mandatory special assessment to the Clerk of Court on or before the date of sentencing.

7. Cooperation

Defendant shall cooperate completely and truthfully in any trial or other proceeding arising out of any ongoing federal grand jury investigation of its current and former officers, agents, and employees. Defendant shall make reasonable efforts to facilitate access to, and to encourage the cooperation of, its current and former officers, agents, and employees for interviews sought by law enforcement agents, upon request and reasonable notice. Defendant shall also take reasonable measures to encourage its current and former officers, agents, and employees to testify truthfully and completely before any grand jury, and at any trial or other hearing, at which they are requested to do so by any government entity.

In addition, Defendant shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the conduct that is within the scope of any ongoing grand jury investigation, trial or other criminal proceeding in the District of Massachusetts, and that are not covered by the attorney-client privilege or work product doctrine.

Provided, however, notwithstanding any provision of this Agreement, that: (1) Defendant is not required to request of its current or former officers, agents, or employees that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Defendant is not required to take any action against its officers, agents, or employees for following their attorney's advice; and (3) Defendant is not required to waive any privilege or claim of work product protection.

8. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

9. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Defendant's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Defendant cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement. If the sentencing judge rejects this Agreement, this Agreement shall be null and void at the option of either the Government or Defendant, with the exception of paragraph 12 which shall remain in full effect.

10. Information For Presentence Report

Defendant agrees to provide all information requested by the U.S. Probation office concerning its assets.

11. Civil and Administrative Liability

By entering into this Agreement, the Government does not compromise any civil or administrative liability, including but not limited to any False Claims Act or tax liability, which Defendant may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Information.

Defendant's civil liability to the United States in connection with certain of the matters under investigation by the Government is resolved in the Civil Settlement Agreement, attached as Exhibit B, according to the terms set forth in that Agreement.

12. Waiver of Defenses

If this Plea Agreement or Defendant's guilty plea is not accepted by the Court for whatever reason, or is later withdrawn or otherwise successfully challenged by Defendant for whatever reason, Defendant hereby waives, and agrees it will not interpose any defense to any charges brought against it which defenses Defendant might otherwise have under any statute of limitations, the Speedy Trial Act, or the United States Constitution with respect to preindictment delay, except that Defendant may raise any such defense that Defendant may have for conduct occurring before August 20, 1999, as further described in the parties tolling agreement dated July 20, 2007, attached hereto as Exhibit C.

13. Withdrawal of Plea by Defendant

Should Defendant move to withdraw its guilty plea at any time, this Agreement shall be null and void at the option of the Government. In this event, Defendant understands and agrees that the Government may pursue any and all charges that might otherwise have been brought but for this Agreement, and Defendant hereby waives, and agrees that will not interpose, any defense to any additional charges brought against it which it might otherwise have under any statute of limitations, the Speedy Trial Act, or the United States Constitution with respect to pre-indictment delay, except any such defense that Defendant may already have for conduct occurring before August 20, 1999.

14. Breach of Agreement

If the Government determines that Defendant has materially failed to comply with any provisions of this Agreement or has committed any crime following its execution of this Agreement, the Government may, at its sole option, be released from its commitments under this Agreement in their entirety by notifying Defendant, through counsel or otherwise, in writing. The Government may also pursue all remedies available to it under the law, irrespective of whether it elects to be released from its commitments under this Agreement. Defendant recognizes that no such material breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. Defendant understands that, should it materially breach any provision of this agreement, the Government will have the right to use against Defendant before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by it, and any information, materials, documents or objects which may be provided by it to the Government subsequent to this Agreement, without any limitation.

Defendant understands and agrees that this 11(c)(1)(C) plea agreement and its agreed upon criminal disposition:

a. are wholly dependent upon Defendant's timely compliance with the provisions of the attached Civil Settlement Agreement, including the requirements in the agreement that Defendant pay to the United States the amount of $485,300, plus any interest due and owing in accord with the terms of the Civil Settlement Agreement; and that

b. failure by Defendant to comply fully with the terms of this Agreement or the attached Civil Settlement Agreement will constitute a breach of this Agreement.

In the event Defendant at any time hereafter materially breaches any provision of this Agreement, Defendant understands that (1) the Government will as of the date of that breach be relieved of any obligations it may have in this Agreement and the attached Civil Settlement Agreement, including but not limited to the promise not to further prosecute Defendant as set forth in paragraph 5 of this Agreement; and (2) Defendant will not be relieved of its obligation to make the payments set forth in this Agreement and the attached Civil Settlement Agreement, nor will it

be entitled to return of any monies already paid. Moreover, in the event of a material breach, Defendant understands and agrees that the Government may pursue any and all charges that might otherwise have been brought but for this Agreement. In this regard, Defendant hereby waives, and agrees that will not interpose, any defense to any additional charges brought against it which it might otherwise have under any statute of limitations, the Speedy Trial Act, or the United States Constitution with respect to pre-indictment delay, except any such defense that Defendant may already have for conduct occurring before August 20, 1999.

15. Who Is Bound By Agreement

This Agreement is limited to the U.S. Attorney for the District of Massachusetts and the Office of Consumer Litigation, U.S. Department of Justice, and cannot and does not bind the Attorney General of the United States or any other federal, state or local prosecutive authorities. The defendant understands that the Agreement does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of Treasury.

16. Corporate Authorization

Defendant shall provide to the Government and the Court a certified copy of a resolution of the Board of Directors of Bryan Corporation, affirming that the Board of Directors has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Bryan Corporation to plead guilty to the charges specified in the Plea Agreement; and (5) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached as Exhibit D. Defendant agrees that either a duly authorized corporate officer or a duly authorized attorney for Bryan Corporation, at the discretion of the Court, shall appear on behalf of Bryan Corporation and enter the guilty plea and will also appear for imposition of sentence.

17. Complete Agreement

This Agreement and the attachments hereto, together with the Civil Settlement Agreement, set forth the complete and only agreement between the Parties relating to the disposition of this matter. No promises, representations, agreements or conditions have been entered into other than those set forth in this Agreement and the attachments hereto, and the Civil Settlement Agreement. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only in a written memorandum signed by the Parties or as agreed by the Parties on the record in court.

If this letter accurately reflects the Agreement between the Government and Bryan Corporation, please have the authorized representative of Bryan Corporation sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Assistant U.S. Attorneys James E. Arnold and Sara Miron Bloom of the United States Attorney's Office for the District of Massachusetts.

Very truly yours,

MICHAEL J. SULLIVAN
United States Attorney

By: _____
DIANE C. FRENIERE, Chief
White Collar Crime Section

_____
JAMES E. ARNOLD
SARA MIRON BLOOM
Assistant U.S. Attorneys

PETER D. KEISLER
Assistant Attorney General
Civil Division
U.S. Department of Justice

_____
KENNETH L. JOST
Deputy Director
Office of Consumer Litigation
U.S. Department of Justice

Acknowledgment of Plea Agreement

The Board of Directors has authorized me to execute this Plea Agreement on behalf of Bryan Corporation. The Board has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement including all attachments in their entirety and has discussed them fully with Bryan Corporation's attorney. The Board acknowledges that this letter fully sets forth Bryan Corporation's agreement with the Government. The Board further states that no additional promises or representations have been made to Bryan Corporation by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated:

BRYAN ABRANO
CEO, President and Sole Director
Bryan Corporation

I certify that Defendant's Board of Directors has passed a resolution to enter into this Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Defendant to plead guilty to the charges specified in the Plea Agreement; and (5) voted to authorize the corporate officer identified above to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement.

Dated: October 23, 2007

T. MARK FLANAGAN, ESQ.
McKenna Long & Aldridge
Attorney for Bryan Corporation

Acknowledgment of Plea Agreement

The Board of Directors has authorized me to execute this Plea Agreement on behalf of Bryan Corporation. The Board has read this Plea Agreement, the attached criminal Information, and the Civil Settlement Agreement including all attachments in their entirety and has discussed them fully with Bryan Corporation's attorney. The Board acknowledges that this letter fully sets forth Bryan Corporation's agreement with the Government. The Board further states that no additional promises or representations have been made to Bryan Corporation by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement and the attached Civil Settlement Agreement.

Dated: OCTOBER 24, 2007

BRYAN ABRANO
CEO, President and Sole Director
Bryan Corporation

I certify that Defendant's Board of Directors has passed a resolution to enter into this Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Defendant to plead guilty to the charges specified in the Plea Agreement; and (5) voted to authorize the corporate officer identified above to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement.

Dated: October 23, 2007

T. MARK FLANAGAN, ESQ.
McKenna Long & Aldridge
Attorney for Bryan Corporation

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	**Crim. No.**
	)	
v.	)	**Violations:**
	)	
BRYAN CORPORATION,	)	**21 U.S.C. §§ 331(a), 333(a)(1) -**
	)	**Interstate Shipment of Misbranded**
	)	**Drugs**
Defendant.	)	
	)	**21 U.S.C. §§ 331(a), 333(a)(1) - Interstate**
	)	**Shipment of Adulterated Devices**
	)	
	)	**18 U.S.C. § 1505 - Obstruction of an**
	)	**Agency Proceeding**

INFORMATION

THE UNITED STATES ATTORNEY CHARGES THAT:

I. GENERAL ALLEGATIONS

At all times material to this Information unless otherwise specified:

1. **BRYAN CORPORATION** was a Massachusetts corporation located in Woburn, Massachusetts, and was engaged in the business of marketing and selling drugs and medical devices.

II. THE FDA AND THE FDCA

2. The United States Food and Drug Administration (hereinafter "FDA") was the agency of the United States responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA") and ensuring, among other things, that drugs and devices intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs and devices bore true and

accurate information. Pursuant to such responsibility, FDA published and administered regulations relating to the approval, manufacture, and distribution of drugs and devices.

3. As part of its mission to enforce the FDCA and protect the public health, FDA had the authority to enter and inspect at reasonable times all establishments where drugs and devices were manufactured, processed, packed, or held for introduction into interstate commerce or after shipment in interstate commerce. 21 U.S.C. § 374.

4. The FDCA prohibited causing the delivery for introduction into interstate commerce of drugs and devices that were not approved or otherwise cleared for use by the FDA. The FDCA also prohibited causing the delivery for introduction into interstate commerce of drugs and devices that were adulterated or misbranded.

A. Prescription Drugs, New Drugs, Misbranded Drugs, Adulterated Drugs and the FDCA

5. Drugs were defined under the FDCA as, *inter alia*, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and articles intended to affect the structure or any function of the body of man. 21 U.S.C. §§ 321(g)(1)(B) and (C).

6. A "new drug" was defined, in relevant part, as a drug that was not generally recognized among qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling. 21 U.S.C. § 321(p).

7. Prescription drugs under the FDCA were, *inter alia*, any drugs intended for use in humans which because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A).

1. Misbranded Drugs

8. Except under certain conditions not applicable here, the FDCA required that adequate directions for use appear on a drug's labeling. 21 U.S.C. § 352(f)(1). Among other things, this required a drug manufacturer to provide adequate information concerning the drug's use, including indications, dosages, and routes, methods, frequency and duration of administration, sufficient to enable a layman to use the drug safely and for the purposes for which it was intended, including all purposes for which it was advertised. Drugs that did not provide this information on their labeling were deemed misbranded. 21 U.S.C. § 352(f)(1).

9. Prior to February 19, 1998, the FDCA required that drugs that were prescription drugs within the meaning of 21 U.S.C. § 353(b)(1)(A), bear on their labels, at all times prior to dispensing, the statement "Caution: Federal law prohibits dispensing without prescription." Effective February 19, 1998, the FDCA required that drugs that were prescription drugs within the meaning of 21 U.S.C. § 353(b)(1)(A) contain on their labels, at all times prior to dispensing, the symbol "Rx only." During the applicable time periods, prescription drugs that failed to bear the required statement or failed to bear the required symbol on their labels were deemed misbranded. 21 U.S.C. § 353(b)(4)(A).

10. Drugs were also misbranded if their labeling was false or misleading in any particular. 21 U.S.C. § 352(a)(1).

2. Adulterated Drugs

11. Under the FDCA, a drug was deemed adulterated if the methods used in, or the controls used for, drug manufacturing, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice and the implementing regulations promulgated by the FDA. 21 U.S.C. § 351(a)(2)(B). *Inter alia*, drug manufacturers selling drugs purporting to be sterile were required to establish and follow appropriate written, validated procedures to prevent microbiological contamination of those drugs. 21 C.F.R. § 211.113(b) (1999). Such drug manufacturers were also required to conduct appropriate laboratory tests to ensure that the finished drug product conformed to its final specifications, that each batch of the drug product was free of objectionable microorganisms, and that the drugs represented as sterile were, in fact, sterile. *See* 21 C.F.R. §§ 211.165(a) and (b), 211.167(a) (1999). Drug batches that failed to meet established standards and specifications were required to be rejected. 21 C.F.R. § 211.165(f) (1999).

B. Devices and the FDCA

12. A device was defined under the FDCA as, *inter alia*, any instrument or implant, including any component, part, or accessory, which was either: (1) intended for use in the cure, mitigation, treatment, or prevention of disease in man; or, (2) intended to affect the structure or function of the body. 21 U.S.C. § 321(h). The FDCA further defined devices as being those articles that did not achieve their primary purposes through chemical action within or on the body, and which were not dependent upon being metabolized for achievement of their primary intended purpose. 21 U.S.C. § 321(h).

13. Devices were classified under different designations. Devices that were not in commercial distribution prior to May 28, 1976, were generally classified as Class III devices, unless they were shown to be substantially equivalent to a device marketed prior to May 28, 1976. 21 U.S.C. § 360c(f)(1).

14. Before a company could market a Class III device, that company was required to submit a premarket approval application to the FDA that provided the FDA with a reasonable assurance that the device was safe and effective for its intended use. 21 U.S.C. §§ 360e(a)(2) and 360e(d)(2).

15. Alternatively, a company could submit a premarket notification, commonly referred to as a "510(k)", to the FDA seeking an upfront determination that the device was "substantially equivalent" to a legally marketed Class I or Class II device. 21 U.S.C. §§ 360c(f) and (i) and 360(k). If the FDA "cleared" the device by determining that the device was substantially equivalent, the company could market the device, which was then considered to be in the same class as the device to which it was compared. 21 U.S.C. § 360c(f)(1).

16. A Class III device was legally deemed to be adulterated if it was not the subject of an approved application for premarket approval and was not exempt from FDA's premarket approval requirements under the exemptions for devices for investigational use. 21 U.S.C. §§ 351(f)(1)(B) and 360j(g).

COUNT I
(21 U.S.C. §§ 331(a), 333(a)(1) -
Interstate Shipment of Misbranded Drugs)

17. The allegations contained in paragraphs 1 through 11 are realleged and incorporated herein by reference.

18. Between in or about March 1997 and on or about September 5, 2000, defendant **BRYAN CORPORATION** sold a product called "Sterile Bulk Talc #1690" and "Sterile Talc Powder #1690" (hereinafter "Product #1690") to hospitals located throughout the United States. Product #1690 consisted of 4 grams of what was represented to be sterile talc powder in either a 125 ml. vial or a 100 ml. vial.

19. Defendant **BRYAN CORPORATION** intended Product #1690 be used in the treatment of patients suffering from pneumothorax and malignant pleural effusion, two painful conditions most commonly associated in patients suffering advanced cancer, congestive heart failure, and pneumonia. Defendant **BRYAN CORPORATION** marketed Product #1690 as a palliative drug to be used by physicians to reduce patients' chest pains, dyspnea and coughing associated with malignant pleural effusion.

20. As promoted by defendant **BRYAN CORPORATION**'s employees orally and in written materials, Product #1690 was to be used to treat such patients in connection with a medical procedure called pleurodesis. Pleurodesis involved the introduction of an irritant such as talc into the pleural surface of the lungs, thereby causing the lining of the lungs to adhere to each other. Product #1690 was to be used as follows: A physician (or others acting on the physician's behalf) first mixed Product #1690 into a liquid "slurry," and then injected the slurry

through a chest tube directly into the patient's chest cavity. Dosage units of talc powder in a slurry ranged from approximately 4 to 8 grams of talc.

21. Product #1690 was a drug within the meaning of 21 U.S.C. §§ 321(g)(1)(B) and (C) in that defendant **BRYAN CORPORATION** marketed the product to be used in the treatment of patients suffering from pneumothorax and malignant pleural effusion. Product #1690 was a prescription drug in that it was not safe to use except under the supervision of a practitioner licensed by law to administer the product because of its potentiality for harmful effect and the method of its use and the collateral measures necessary to its use. *See* 21 U.S.C. § 353(b)(1)(A).

22. At all times material to this Information, Product #1690 was also a "new drug" because it was not generally recognized as safe and effective by qualified experts to be used in the treatment of patients suffering from pneumothorax and malignant pleural effusion.

23. Because the talc contained in Product #1690 was mined directly from the earth and was intended to be used internally in critically ill patients -- many of whom had compromised immune systems -- it was imperative that the talc powder be tested prior to commercial release to ensure that the product was completely and properly sterilized.

24. At no time between in or about March 1997 and on or about September 5, 2000, did defendant **BRYAN CORPORATION** submit a new drug application or investigational new drug application to the FDA for Product #1690, and the FDA had not otherwise approved distribution of Product #1690.

25. Defendant **BRYAN CORPORATION** arranged for a contract drug manufacturer located in Hicksville, New York, to package Product #1690 in vials containing 4 grams of talc

powder. After the contract drug manufacturer packed the talc powder into vials, defendant **BRYAN CORPORATION** arranged with a separate contract facility located in Northborough, Massachusetts, to subject the talc to gamma radiation in an attempt to sterilize the talc powder.

26. Defendant **BRYAN CORPORATION** contracted with a testing laboratory in Bedford, Massachusetts, to conduct sterility tests on each lot of Product #1690.

27. On multiple occasions, defendant **BRYAN CORPORATION** shipped to hospitals in interstate commerce vials of Product #1690 that were adulterated in that **BRYAN CORPORATION** shipped the vials of Product #1690 prior to the completion of the sterility tests associated with the lot. In addition, on multiple occasions, defendant **BRYAN CORPORATION** shipped to hospitals in interstate commerce vials of Product #1690 that were adulterated in that defendant **BRYAN CORPORATION** shipped lots 9H010 and 9K012 of Product #1690 after receiving test results indicating that those lots had tested non-sterile.

28. At no time between in or about March 1997 and February 18, 1998, did defendant **BRYAN CORPORATION** cause to be placed on the label of Product #1690 the statement "Caution: Federal law prohibits dispensing without a prescription." Similarly, at no time between February 19, 1998, and on or about September 5, 2000, did **BRYAN CORPORATION** cause to be placed on the label of Product #1690 the symbol "Rx only."

29. At no time between in or about March 1997 and on or about September 5, 2000, did defendant **BRYAN CORPORATION** include on Product #1690's labeling sufficient directions concerning the drug's use to enable a layman to administer the drug safely and for the purposes for which it was intended.

30. Between in or about March 1997 and on or about September 5, 2000, in the District of Massachusetts and elsewhere,

BRYAN CORPORATION,

defendant herein, did cause to be introduced and delivered for introduction into interstate commerce various quantities of a misbranded and unapproved new drug -- to wit, approximately $3,762,235 worth of Product #1690. Product #1690 was misbranded in that (a) it lacked adequate directions for use as required by 21 U.S.C. § 352(f)(1); (b) its label did not bear the statement "Caution: Federal law prohibits dispensing without prescription" and did not bear the symbol "Rx only" as required by 21 U.S.C. § 353(b)(4)(A); and (c) with respect to Lots 9H010 and 9K012, its labeling was false and misleading within the meaning of 21 U.S.C. § 352(a)(1) in that the labeling represented that these lots were sterile notwithstanding the fact that **BRYAN CORPORATION** well knew that an independent testing laboratory had determined that the lots had tested non-sterile.

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1).

COUNT II
(21 U.S.C. §§ 331(a), 333(a)(1) - Interstate Shipment of Adulterated Devices)

31. The allegations contained in paragraphs 1 through 4 and paragraphs 12 through 16 are realleged and incorporated herein by reference.

32. Beginning in or about 1998 and continuing thereafter, defendant **BRYAN CORPORATION** sold a medical device that, at some point in time, defendant **BRYAN CORPORATION** marketed under the name "Biotrace." Biotrace was a sterile barium sulfate powder that defendant **BRYAN CORPORATION** sold that could be mixed with bone cement as a radiopacifier for imaging purposes -- that is, Biotrace was marketed as an additive to bone cement in order to allow physicians who were using bone cement to repair compression fractures in patients' vertebrae to be able to see the bone cement during the medical procedure. Defendant **BRYAN CORPORATION** marketed two forms of this device: Biotrace Model 1730, which contained 6 grams of sterile barium sulfate, and Biotrace Model 1740, which contained 15 grams of sterile barium sulfate.

33. Both Biotrace Model 1730 and Biotrace Model 1740 were devices within the meaning of Title 21, United States Code, § 321(h) in that they were accessories to a device that was intended to affect the structure or function of the body, they did not achieve primary purpose through chemical action within or on the body, and they were not dependent upon being metabolized for achievement of their intended primary purpose.

34. Beginning no later than in or about 1998, defendant **BRYAN CORPORATION** began selling the product ultimately called Biotrace Model 1730 in interstate commerce. At that time, the FDA had not approved or cleared Biotrace Model 1730 for commercial distribution in the United States.

35. In or around the end of March 2000, defendant **BRYAN CORPORATION** submitted to the FDA an abbreviated premarket notification for Biotrace Model 1730. The FDA acknowledged receipt of this premarket notification in a letter dated March 30, 2000, and warned defendant **BRYAN CORPORATION** in that letter that "YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO."

36. In or about June 2000, defendant **BRYAN CORPORATION** withdrew its abbreviated premarket notification for Biotrace Model 1730. In response, the FDA sent a letter dated June 27, 2000, to defendant **BRYAN CORPORATION** acknowledging receipt of the withdrawal of defendant **BRYAN CORPORATION**'s premarket notification for Biotrace Model 1730. In that letter, the FDA again warned defendant **BRYAN CORPORATION** that it could not commercially distribute Biotrace Model 1730 until it had received a letter from the FDA allowing it to do so: "You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance/approval, you will be in violation of the Federal Food, Drug, and Cosmetic Act."

37. On or about June 29, 2000, defendant **BRYAN CORPORATION** submitted a traditional (non-abbreviated) premarket notification to the FDA for Biotrace Model 1730. In response, the FDA issued a letter dated July 7, 2000, in which the FDA both acknowledged receipt of the traditional premarket notification and again advised defendant **BRYAN CORPORATION** that it could not commercially distribute the device until the FDA cleared the Biotrace Model 1730 for commercial distribution: "YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO." The FDA provided that clearance on August 10, 2000.

38. Despite the various notices from the FDA that defendant **BRYAN CORPORATION** could not commercially distribute Biotrace Model 1730 until the FDA approved or otherwise cleared the device, defendant **BRYAN CORPORATION** continued selling Biotrace Model 1730 in interstate commerce. Between in or about December 1997 and August 10, 2000, when the FDA cleared the device, defendant **BRYAN CORPORATION** sold approximately $778,922 worth of Biotrace Model 1730; of that total, approximately $316,015 of those sales occurred after on or about March 30, 2000, when the FDA first informed defendant **BRYAN CORPORATION** in writing that it could not commercially distribute the device.

39. Beginning in or about May 1999 and continuing through in or about November, 2000, defendant **BRYAN CORPORATION** sold its other sterile barium sulfate product, Biotrace Model 1740, to hospitals throughout the United States. At no time did defendant **BRYAN CORPORATION** seek or have premarket approval or clearance from the FDA to sell Biotrace Model 1740. During this time, defendant **BRYAN CORPORATION** sold approximately $39,850 worth of Biotrace Model 1740.

40. Between in or about December 1997 and in or about November 2000, in the District of Massachusetts and elsewhere,

BRYAN CORPORATION,

defendant herein, did introduce and deliver for introduction, and cause the introduction and delivery for introduction, into interstate commerce various quantities of Biotrace Model 1730 and Biotrace Model 1740 that were adulterated devices within the meaning of 21 U.S.C. § 351(f)(1)(B), in that these devices were Class III devices that required premarket approval

from FDA and these devices did not have FDA approval and were not exempt from such approval.

All in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 351(f)(1)(B).

COUNT THREE
(18 U.S.C. § 1505 - Obstruction of an Agency Proceeding)

41. The allegations contained in paragraphs 1 through 16, paragraphs 18 through 29, paragraphs 32 through 34, and paragraph 39 are realleged and incorporated herein by reference.

42. Between on or about March 1 and on or about March 9, 2000, an FDA investigator conducted an inspection of defendant **BRYAN CORPORATION's** facility in Woburn, Massachusetts, pursuant to FDA's statutory inspection authority set forth at 21 U.S.C. § 374. During this inspection of defendant **BRYAN CORPORATION**, the FDA investigator sought to review various documents pertaining to product complaints and returned goods.

43. In response to the FDA investigator's request to review documents and in an attempt to conceal from the FDA investigator the fact that defendant **BRYAN CORPORATION** was distributing unapproved, misbranded, and uncleared product, defendant **BRYAN CORPORATION's** employees created a new, false Returned Goods Authorization log that omitted reference to unapproved and misbranded drugs, namely Product #1690 (sterile talc powder), and unapproved and uncleared devices, namely Biotrace Models 1730 and 1740 (barium sulfate). An employee of defendant **BRYAN CORPORATION** subsequently presented this fabricated and false Returned Goods Authorization log to the FDA investigator during the FDA inspection.

44. Employees of defendant **BRYAN CORPORATION** also made false statements and hid evidence from the FDA investigator during the inspection -- including falsely describing the whereabouts of Bryan Corporation's owner and president, moving product off-site, and hiding documents -- to conceal from the FDA the fact that **BRYAN CORPORATION** was distributing unapproved, misbranded, and uncleared product.

45. Between on or about March 1, 2000, and on or about March 9, 2000, in the District of Massachusetts and elsewhere,

BRYAN CORPORATION,

defendant herein, corruptly obstructed, impeded, and endeavored to influence the due and proper administration of the law under which a pending proceeding was being had before an agency of the United States, to wit, an inspection by the FDA of **BRYAN CORPORATION**, by causing the withholding and concealing of information concerning the unapproved and misbranded drug Product #1690 and the unapproved and uncleared device Biotrace Models 1730 and 1740 being distributed by defendant **BRYAN CORPORATION**.

All in violation of Title 18, United States Code, Section 1505.

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: _____
JAMES E. ARNOLD
SARA MIRON BLOOM
ASSISTANT UNITED STATES ATTORNEYS

Date: _____

EXHIBIT B

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice (the "United States"), and Bryan Corporation ("Bryan") (hereafter referred to as "the Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. Bryan Corporation is a company located in Woburn, Massachusetts that distributes drugs and medical devices;

B. The United States contends that Bryan submitted or caused to be submitted claims for payment to the United States for sales of its products to the United States;

C. The United States contends that it has certain civil claims, as specified in Paragraph 2 below, against Bryan for engaging in the following conduct during the period from January 1, 1997 through 2000 (hereinafter the conduct described in this paragraph and subparagraphs (1) - (3) below will be referred to as the "Covered Conduct"):

(1) Bryan sold a new drug (Product # 1690) that it called "sterile bulk talc" to the United States, when that drug was not approved by the FDA and when that drug was not manufactured in conformance with current Good Manufacturing Practice requirements, see 21 C.F.R. Parts 210 and 211, and specifically had not been properly sterilized and had not passed required sterility testing;

(2) Bryan sold a drug known as Sclerosol (Product # 1680) to the United States when that drug was not manufactured in conformance with current Good

Manufacturing Practice requirements and specifically was shipped prior to the completion of required sterility testing; and

(3) Bryan sold devices known as barium sulfate (Biotrace Model 1730 and 1740) to the United States, when those devices were not manufactured in conformance with current Good Manufacturing Practice requirements and specifically had not been approved or cleared for sale by the FDA;

D. On or before October 31, 2007, or such other date as may be determined by the Court, Bryan has agreed to enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in the District of Massachusetts (the "Criminal Action") that will allege violations of Title 18 U.S.C. § 1505 and Title 21 U.S.C. §§ 331, 333(a)(1);

E. This Agreement is neither an admission of liability by Bryan nor a concession by the United States that its civil claims are not well founded;

F. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

1. Bryan agrees to pay to the United States $485,300, plus interest at the Prompt Payment Act Rate in effect on July 15, 2006, from July 15, 2006 until the date of payment (the "Settlement Amount"). Bryan agrees to pay the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of Massachusetts. Bryan agrees to make this electronic funds transfer no later than seven business days following the latest of the dates on which the following occurs:

(1) this Agreement is fully executed by the Parties and delivered to Bryan's attorneys; or (2) 90 days following the date on which the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Preamble D in connection with the Criminal Action and imposes the agreed upon sentence.

2. Subject to the exceptions in Paragraph 3 below, in consideration of the obligations of Bryan set forth in this Agreement, conditioned upon Bryan's full payment of the Settlement Amount, and subject to Paragraph 10 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Bryan, together with its current and former parent corporations, each of its direct and indirect subsidiaries, brother or sister corporations, divisions, current or former owners, officers, directors, employees, agents, and the successors and assigns of any of them, from any civil or administrative monetary claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* or the common law theories of payment by mistake, unjust enrichment, breach of contract, and fraud, for the Covered Conduct.

3. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Bryan) are the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon such obligations as are created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services; and

g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

4. Bryan waives and will not assert any defenses Bryan may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Settlement Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

5. Bryan fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Bryan has asserted, could have asserted, or may assert in

the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The Settlement Amount will not be decreased as a result of the denial of claims for payment now being withheld from payment by any government entity, Medicare carrier or intermediary or any State payer, related to the Covered Conduct; and Bryan agrees not to resubmit to any government entity, Medicare carrier or intermediary or any State payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

7. Bryan agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Bryan, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program ("FEHBP"):

(1) the matters covered by this Agreement and any related plea agreement,

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement,

(3) Bryan's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),

(4) the negotiation and performance of this Agreement and any Plea Agreement, and

(5) the payment Bryan makes to the United States pursuant to this Agreement, including any costs and attorneys fees.

(b) Future Treatment of Unallowable Costs: Bryan will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Bryan or any of its subsidiaries to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: Bryan further agrees that within 90 days of the effective date of this Agreement it will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, if any, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Bryan or any of its subsidiaries or affiliates, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Bryan agrees that the United States, at a minimum, will be entitled to recoup from Bryan any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Bryan or any of

its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Bryan or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

8. Except as otherwise expressly stated, this Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 2 and 5.

9. Bryan warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Bryan, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity to which Bryan was or became indebted, on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

10. If, within 91 days of the effective date of this Agreement, Bryan commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of Bryan's debts, or seeking to adjudicate Bryan as bankrupt or insolvent; or (b)

seeking appointment of a receiver, trustee, custodian, or other similar official for Bryan or for all or any substantial part of Bryan's assets, Bryan agrees as follows:

(a) Bryan's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Bryan will not argue or otherwise take the position in any such case, proceeding, or action that: (i) Bryan's obligations under this Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) Bryan was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Bryan.

(b) If Bryan's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Bryan for the claims that would otherwise be covered by the releases provided in Paragraphs 2-3, above. Bryan agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Bryan from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. Section 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that Bryan will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that Bryan will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 90 calendar days of written notification to Bryan that the

releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on August 20, 2004; and (iii) the United States has a valid claim against Bryan in the amount of $ 650,000, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

(c) Bryan acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

11. Bryan represents that Frank Abrano has resigned as an officer and director of Bryan, and has retained only the authority through his ownership of shares of Bryan to enter into a transaction to relinquish all of his ownership interest in Bryan, through either a sale of his shares or a sale of the company's assets, which Bryan agrees shall occur within 90 days from the effective date of this Agreement. Bryan agrees that following the relinquishment of Frank Abrano's ownership interest as set forth above, it will not employ or otherwise permit Frank Abrano, directly or indirectly, to provide any services to or have any affiliation with Bryan, and that Bryan will not allow Frank Abrano to exercise any control, directly or indirectly, or have any ownership interest over Bryan or any of its operations for a period of twenty years from the effective date of this Agreement.

12. Each Party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. Bryan represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

14. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the District of Massachusetts.

15. This Agreement and the Plea Agreement referenced in Preamble D constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

16. The individuals signing this Agreement on behalf of Bryan represent and warrant that they are authorized by Bryan to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

17. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

18. This Agreement is binding on Bryan's successors, transferees, heirs, and assigns.

19. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

20. This Agreement is effective on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

THE UNITED STATES OF AMERICA

DATED: 12/6/07

BY: _____
Sara Miron Bloom
Assistant United States Attorney

District of Massachusetts

Bryan Corporation - DEFENDANT

DATED: _____

BY: _____
Bryan Abrano
Bryan Corporation CEO, President and Sole Director

DATED: 10/23/07

BY: _____
Mark Flanagan
Counsel for Bryan Corporation

20. This Agreement is effective on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

THE UNITED STATES OF AMERICA

DATED:_____ BY: _____
Sara Miron Bloom
Assistant United States Attorney

District of Massachusetts

Bryan Corporation - DEFENDANT

DATED: 10/24/07 BY: _____
Bryan Abramo
Bryan Corporation CEO, President and Sole Director

DATED: 10/23/07 BY: _____
Mark Flanagan
Counsel for Bryan Corporation

EXHIBIT C

U.S. Department of Justice

United States Attorney
District of Massachusetts

Main Reception: (617) 748-3100

United States Courthouse, Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210

July 20, 2007

Mr. Mark Flanagan, Esq.
McKenna Long & Aldridge
1900 K Street, NW
Washington, DC 20006

Re: Bryan Corporation: Tolling Agreement on Statute of Limitations

Dear Mr. Flanagan:

This letter confirms and sets forth an agreement between the Office of the United States Attorney for the District of Massachusetts and your client, Bryan Corporation. The terms of the agreement are as follows:

1. As you are aware, this Office is presently conducting a joint criminal and civil investigation of your client, Bryan Corporation, and certain of its officers, employees, and agents. The conduct being investigated includes, without limitation, allegations that Bryan Corporation and certain of its officers, employees, and agents may have violated various federal criminal statutes, including, but not limited to 18 U.S.C. § 371 (conspiracy to defraud the United States), 18 U.S.C. § 1001 (making false or fraudulent statements), 21 U.S.C. §§ 301, et seq. (Food Drug & Cosmetic Act), mail and/or wire fraud (18 U.S.C. §§ 1341, 1343), obstruction of justice (18 U.S.C. § 1505), and certain civil statutes including but not limited to 31 U.S.C. § 3729 (civil False Claims Act) in connection with (a) Bryan Corporation's distribution in interstate commerce of a prescription drug (talc powder) that was adulterated, misbranded, and had not yet been approved for commercial distribution by the United States Food and Drug Administration ("FDA") during the time period prior to 2003, (b) Bryan Corporation's distribution of a medical device (barium sulfate) that had not yet been approved by the FDA; and (c) the obstruction of an agency proceeding (namely, an FDA inspection of the Bryan Corporation) during March 2000. Furthermore, as we advised you, the investigation also is looking into whether Bryan Corporation shipped in interstate commerce adulterated prescription drugs (Sclerosol) and/or adulterated medical devices (barium sulfate).

2. This Office and your client have agreed, as more fully set forth below, to toll the applicable statutes of limitations for the time period from August 20, 2004 (the date on which

you and your client first executed a statute of limitations tolling agreement), through and including October 31, 2007, for the conduct noted in paragraph one.

3. This Office and your client, Bryan Corporation hereby agree that your client will not at any time interpose a statute of limitations defense or any constitutional claim based upon pre-indictment delay to any indictment, informations, or count thereof, to any civil complaint, or counts thereof, or to any administrative action, which charges your client with any federal crime or violation of federal law related to the conduct described in Paragraph 1, that includes the time period from August 20, 2004, through October 31, 2007, in the calculation of the limitations period. Nothing herein shall affect, or be construed as a waiver of, any other applicable defenses that your client may have during the time period prior to your client's execution of this agreement, and your client expressly reserves its right to raise any such defense, any provisions of this agreement notwithstanding, except to the extent that your client has waived certain defenses in any Statute of Limitations waiver agreements or subsequent written agreements executed between this Office and your client in connection with this investigation, which agreements provided for waivers through August 3, 2007. Any such agreements remain effective as of this date.

4. Your client, Bryan Corporation, enters into this agreement knowingly and voluntarily. Bryan Corporation acknowledges that the statute of limitations and the United States Constitution regarding prejudicial pre-indictment delay confers benefits on it, and it is not required to waive those benefits, and that Bryan Corporation is doing so after consulting with you because Bryan Corporation believes it is in its best interest to do so. Bryan Corporation also acknowledges its understanding that it may be charged with the foregoing offenses or violations and/or any other offenses at any time prior to and including October 31, 2007. Bryan Corporation further acknowledges its understanding that it may be charged with any criminal or civil offenses for conduct not specifically described above, at any time during the relevant statute of limitations period. Your client also acknowledges that by signing this agreement, it is waiving any argument that it may have that (1) the Government may, in any way, have breached the prior statute of limitations waiver agreements executed between this Office and your client in connection with this investigation, or (2) that any such breach may provide it with any defense to any charges arising out of the conduct described in paragraph one that may be brought against it.

5. This agreement relates only to the conduct referred to in paragraph one above. This writing contains the entire agreement between this Office and your client and can be modified or supplemented only by means of a writing signed by this Office and your client.

If your client is willing to enter into this agreement on the terms set forth above, the duly appointed representative of the Bryan Corporation should indicate the same by signing on the spaces provided below and by initialing each page of this agreement. Please return an executed original to the undersigned.

Very truly yours,

MICHAEL J. SULLIVAN
United States Attorney

By: /s/ Sara Bloom
SARA MIRON BLOOM
JAMES E. ARNOLD
Assistant U.S. Attorneys

I, FRANK ABRANO am CEO of the Bryan Corporation and I hereby acknowledge that I have read this letter in full. I am entering into this agreement freely and voluntarily after consultation with Bryan Corporation's attorney, who has also signed below. I hereby disclose and represent that I am authorized by the Bryan Corporation to enter into this agreement on behalf of the corporation. On behalf of Bryan Corporation I hereby acknowledge that it is giving up certain benefits contained in the statute of limitations and in the United States Constitution as to its potential criminal and civil culpability and that the company does so because it believes that doing so is in its best interests.

Dated: July 27, 2007

Duly authorized representative of Bryan Corporation

I have consulted with my client, Bryan Corporation, concerning this agreement. I have explained the agreement and its terms to its authorized representative and have recommended that Bryan Corporation enter into it. I believe that Bryan Corporation is entering into this agreement freely, voluntarily, and knowingly.

Mark Flanagan /em Dated: July 23, 2007

Mark Flanagan, Esq.
Counsel to Bryan Corporation

EXHIBIT D

BRYAN CORPORATION
CERTIFICATE

I, Bryan Abrano, hereby certify that I am Chief Executive Officer, President and sole member of the Board of Directors of Bryan Corporation (the "Company"). As sole member of the Board of Directors, I hereby have adopted the following Resolution on behalf of the Company which is in full force and effect on the date hereof, and has not been modified, amended, or rescinded.

> RESOLVED, that Bryan Abrano, Chief Executive Officer, President and sole member of the Board of Directors of Bryan Corporation, and Mark Flanagan of McKenna Long & Aldridge LLP, are authorized on behalf of the Company to appear in the United States District Court for the District of Massachusetts to waive the Company's right to indictment, to enter a plea in accordance with the Plea Agreement between the Company and the United States, and to take such actions as are necessary or appropriate under the Plea Agreement. The authorization of Messrs. Abrano and Flanagan includes assigning to them the Power of Attorney to execute and deliver such instruments and documents on behalf of the Company which are necessary for the performance of the entry of the Plea.

By: _____
Bryan Abrano
Chief Executive Officer, President and
Sole Member of the Board of Directors

Date: 10/18/07

Subscribed and sworn to before me this 18 day of October 2007.

_____
Notary Public

My Commission Expires: 11/29/2007

DC:50505405.1

PAULA J. ZARBANO
Notary Public
Commonwealth of Massachusetts
My Commission Expires Nov. 29, 2007